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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/457,421	12/07/1999	ALAN A. DAVIS	AHP92038-2-C	7663
25291	7590	12/03/2003	EXAMINER	
WYETH PATENT LAW GROUP FIVE GIRALDA FARMS MADISON, NJ 07940			LE, EMILY M	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/457,421

Applicant(s)

DAVIS ET AL.

Examiner

Emily Le

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/14/03, Amendment with Election.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 26-39, in the Amendment with a mailing of 10/14/03 is acknowledged.

Status of Claims

Claims 17-25 are canceled by Applicant in the Amendment with a mailing of 10/14/03.

Claims 26-39 are pending and are under examination.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "range of about" in claims 34-36 is a relative term which renders the claim indefinite. The term "range of about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Thus, it is unclear what the metes and bounds are of "the range about" is. An amendment to the claims to recite "the range", deleting "about" would obviate this rejection.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 26-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,511,845.

Claims 26-27, and 38-39 of the instant application is the same as claim 1 and claim 13 of the conflicting patent. The claims in both instances are directed to a

method of producing an immune response against HIV-1 infection in a human comprising administering to said human an intranasal or intramuscular dosage of a recombinant adenovirus having a deletion in the E3 gene comprising an expression cassette containing a major late promoter, part or all of the HIV gp160 sequence and a polyadenylation signal sequence, wherein the administration of the recombinant adenovirus is followed by one or more intranasal or intramuscular booster administration of said recombinant adenovirus.

The difference between claims 26-27 and 38 of the instant application and claim 1 and claim 13 of the conflicting patent is that claim 1 of the conflicting patent includes a tripartite leader sequence and the location of the cassette, which is inserted into said recombinant adenovirus between the E4 promoter and the inverted terminal repeat of said recombinant adenovirus.

Also, claim 39 of the instant application further recites a deletion of the E1 OR E5 gene in addition to a deletion in the E3 gene of the recombinant adenovirus. These are obvious but not distinct differences. One of ordinary skills in the art would not conclude that the invention of the instant application is different from that of the conflicting difference.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the instant application are generic to the claim in the conflicting patent. The claims recited in the patent falls entirely within the scope of the examining claims.

Claims 26-28 and 38-39 of the instant application is the same as claims 1,6 and claim 13 of the conflicting patent. The relevance of claims 26-27, and 38-39 of the instant application and claim 1 and claim 13 of the conflicting patent is discussed above.

Claim 28 of the instant application is the same as claim 6 of the conflicting patent. Both claims are directed to the addition of an intramuscular injection of at least one booster immunization with an HIV-1 antigen preparation, wherein the preparation contains HIV-1 gag and/or env polypeptide sequence, which follows the one or more intranasal or intramuscular booster administration of the recombinant adenovirus.

The difference between claim 28 of the instant application and claim 6 of the conflicting patent is that claim 6 of the instant application also recites a combination of gag and env polypeptide as an additional possible preparation for the HIV-1 antigen.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the instant application are generic to the claim in the conflicting patent. Claim 28 of the instant application recite that the HIV-1 antigen preparation is a gag polypeptide, env polypeptide, OR a combination thereof, where the choice of a gag polypeptide and env polypeptide is the same as that recited in claim 6 of the conflicting patent. The claims recited in the patent falls entirely within the scope of the examining claims.

Claims 26-27, 29 and 38-39 of the instant application is the same as claims 1, 2 and claim 13 of the conflicting patent. The relevance of claims 26-27, and 38-39 of the instant application and claim 1 and claim 13 of the conflicting patent is discussed above.

Claim 29 of the instant application is the same as claim 2 of the conflicting patent. Both claims are further limiting to serotype 4, 5 or 7 serotype adenovirus.

Claims 26-27, 30 and 38-39 of the instant application is the same as claims 1, 3, and 13 of the conflicting patent. The relevance of claims 26-27, and 38-39 of the instant application and claim 1 and claim 13 of the conflicting patent is discussed above.

Claim 30 of the instant application is the same as claim 6 of the conflicting patent. Both claims are directed to the addition of part or all of the coding sequence for the HIV-1 rev gene inserted in frame after the HIV-1 gp160 sequence and before the polyadenylation signal sequence.

Claims 26-27, 31 and 38-39 of the instant application is the same as claims 1, 4, and 13 of the conflicting patent. The relevance of claims 26-27, and 38-39 of the instant application and claim 1 and claim 13 of the conflicting patent is discussed above.

Claim 31 of the instant application is the same as claim 4 of the conflicting patent. Both claims are directed to further defining the strain of gp160 sequence, which is the MN strain gp160 sequence OR the LAV strain gp160 sequence.

Claims 26-27, 32 and 38-39 of the instant application is the same as claims 1, 5 and 13 of the conflicting patent. The relevance of claims 26-27, and 38-39 of the instant application and claim 1 and claim 13 of the conflicting patent is discussed above.

Claim 32 of the instant application is the same as claim 5 of the conflicting patent. Both claims are directed replacing the HIV-1 gp160 sequence with a sequence that encodes the gag-pro region of HIV-1.

Claims 26-27, 33 and 38-39 of the instant application is the same as claims 1, 7, and 13 of the conflicting patent. The relevance of claims 26-27, and 38-39 of the instant application and claim 1 and claim 13 of the conflicting patent is discussed above.

Claim 33 of the instant application is the same as claim 7 of the conflicting patent. Both claims are directed the dosage of the intranasal administered, which is 1×10^7 pfu of virus.

Claims 26-27, 35 and 38-39 of the instant application is the same as claims 1, 8, and 13 of the conflicting patent. The relevance of claims 26-27, and 38-39 of the

instant application and claim 1 and claim 13 of the conflicting patent is discussed above.

Claim 35 of the instant application is the same as claim 8 of the conflicting patent. Both claims are directed the dosage of the intranasal booster administered, which is 1×10^7 to 1×10^8 pfu of virus.

Claims 26-27, 36 and 38-39 of the instant application is the same as claims 1, 13, and 21 of the conflicting patent. The relevance of claims 26-27, and 38-39 of the instant application and claim 1 and claim 13 of the conflicting patent is discussed above.

Claim 36 of the instant application is the same as claim 21 of the conflicting patent. Both claims are directed the dosage of the intramuscular booster administered, which is 1×10^{10} to 8×10^{10} pfu of virus.

Claims 26-27, and 37-39 of the instant application is the same as claims 1, 10, and 13 of the conflicting patent. The relevance of claims 26-27, and 38-39 of the instant application and claim 1 and claim 13 of the conflicting patent is discussed above.

Claim 37 of the instant application is the same as claim 10 of the conflicting patent. Both claims are directed the dosage of HIV-1 antigen preparation, which is between 200 μ g and .5mg.

Thus, in view of the claims recited in U.S. Patent No. 6,511,845 B1 and the explanation set forth in this office action the instant application is subjected to an obvious nonstatutory double patenting rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (703) 305-4452. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0169.

E.Le



HANKYEL T. PARK, PH.D
PRIMARY EXAMINER